



PTO/SB/08a (08-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/601,953
Filing Date	6/24/2003
First Named Inventor	Quay
Art Unit	1614
Examiner Name	
Attorney Docket Number	02-03US

Sheet 1 of 15

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Document Number	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
ADK		US- 5,554,388	Issued 09-10-1996	Danbiosyst UK Limited	
		US- 5,629,011	Issued 05-13-1997	Danbiosyst UK Limited	
		US- 5,744,166	Issued 04-28-1998	Danbiosyst UK Limited	
		US- 5,935,604	Issued 08-10-1999	Danbiosyst UK Limited	
		US- 6,048,536	Issued 04-11-2000	Medeva Holdings BV	
		US- 6,110,747	Issued 08-29-2000	Adherex Technologies, Inc.	
		US- 6,136,806	Issued 10-24-2000	Medeva Holdings BV	
		US- 6,228,396	Issued 05-08-2001	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
ADK		US- 6,248,864	Issued 06-19-2001	Adherex Technologies, Inc.	
		US- 6,342,251	Issued 01-29-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,391,318	Issued 05-21-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre	
ADK		US- 6,383,513	Issued 05-07-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
ADK		WO 90/09780 (International Application Number PCT/GB90/00291)	09-07-1990	Danbiosyst UK Limited		
		WO 93/15737 (International Application Number PCT/GB93/00228)	08-19-1993	Danbiosyst UK Limited		
		WO 95/35100 (International Application Number PCT/GB95/01458)	12-28-1995	Danbiosyst UK Limited		
		WO 98/47535 (International Application Number PCT/GB98/01147)	10-29-1998	Danbiosyst UK Limited		
		WO 99/27905 (International Application Number PCT/GB98/03572)	06-10-1999	Danbiosyst UK Limited		
		WO 03/080021 (International Application Number PCT/GB03/01183)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
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ADK		US- 6,387,917	Issued 05-14-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
ADK		US- 6,432,440	Issued 08-13-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

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ADK		WO 03/080022 (International Application Number PCT/GB03/01184)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd.		
ADK		WO 2004/062561 (International Application Number PCT/GB2004/000057)	07-29-2004	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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ADK		ARMSTRONG et al, "Clinical Modulation of Oral Leukoplakia and Protease Activity by Bowman-Birk Inhibitor Concentrate in a Phase IIa Chemoprevention Trial," <i>Clinical Cancer Research</i> , December 2000, vol. 6 no. 12, pages 4684-4691.	
		TOMEE et al, "Secretory leukoprotease inhibitor: a native antimicrobial protein presenting a new therapeutic option?" <i>Thorax</i> , February 1998, vol. 53 no. 2, pages 114-116.	
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		RAO et al, "Interaction of Secretory Leukocyte Protease Inhibitor with Proteinase-3," <i>American Journal of Respiratory Cell and Molecular Biology</i> , June 1993, vol. 8 no. 6, pages 612-616.	
		THOMSON and OHLSSON, "Isolation, properties, and complete amino acid sequence of human secretory leukocyte protease inhibitor, a potent inhibitor of leukocyte elastase," <i>Proc. Natl. Acad. Sci. USA</i> , September 1986, vol. 83 no. 18, pages 6692-6696.	
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		ILLUM et al, "Chitosan as a Novel Nasal Delivery System for Peptide Drugs," <i>Pharmaceutical Research</i> , 1994, vol. 11 no. 8, pages 1186-1189, Plenum Publishing Corporation.	
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ADK		KARLSSON et al, "Paracellular drug transport across intestinal epithelia: influence of charge and induced water flux," <i>European Journal of Pharmaceutical Sciences</i> , October 1999, vol. 9, no. 1, pages 47-56.	

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ADK		DUIZER et al, "Absorption Enhancement, Structural Changes in Tight Junctions and Cytotoxicity Caused by Palmitoyl Carnitine in Caco-2 and IEC-18 Cells," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , October 1998, vol. 287, no. 1, pages 395-402.		
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		DREJER et al, "Intranasal Administration of Insulin With Phospholipid as Absorption Enhancer: Pharmacokinetics in Normal Subjects," <i>Diabetic Medicine</i> , 1992, vol. 9, pages 335-340.		
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		NEGRI et al, "Glycodermorphins: opioid peptides with potent and prolonged analgesic activity and enhanced blood-brain barrier penetration," <i>British Journal of Pharmacology</i> , 1998, vol. 124, pages 1516-1522, Stockton Press.		
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		POLT et al, "Glycopeptide enkephalin analogues produce analgesia in mice: Evidence for penetration of the blood-brain barrier," <i>Proc. Natl. Acad. Sci. USA</i> , July 1994, vol. 91, pages 7114-7118, Pharmacology.		
ADK		TAMAI et al, "Structure-Internalization Relationship for Adsorptive-Mediated Endocytosis of Basic Peptides at the Blood-Brain Barrier," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 1997, vol. 280, no. 1, pages 410-415.		

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Sheet	5	of	15	Attorney Docket Number	02-03US

NON PATENT LITERATURE DOCUMENTS			
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ADK		TSUZUKI et al, "Adamantane as a Brain-Directed Drug Carrier for Poorly Absorbed Drug. 2. AZT Derivatives Conjugated with the 1-Adamantane Moiety," <i>Journal of Pharmaceutical Sciences</i> , April 1994, vol. 83, no. 4, pages 481-484.	
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		FASANO, "Modulation of Intestinal Permeability: An Innovative Method of Oral Drug Delivery for the Treatment of Inherited and Acquired Human Diseases," <i>Molecular Genetics and Metabolism</i> , May 1998, vol. 64, pages 12-18, Academic Press.	
		FASANO and UZZAU, "Modulation of Intestinal Tight Junctions by Zonula Occludens Toxin Permits Enteral Administration of Insulin and Other Macromolecules in an Animal Model," <i>J. Clin. Invest.</i> , March 1997, vol. 99, no. 6, pages 1158-1164.	
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ADK		HIRAI et al, "Mechanisms for the enhancement of the nasal absorption of insulin by surfactants," <i>International Journal of Pharmaceuticals</i> , 1981, vol. 9, pages 173-184, Elsevier/North-Holland Biomedical Press.	

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		LEE et al, "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 1991, vol. 8, no. 2, pages 91-192, CRC Press, Inc.		
		MISHIMA et al, "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats," <i>J. Pharmacobio-Dyn.</i> , 1987, vol. 10, pages 624-631.		
		NAGAI et al, "Powder Dosage Form of Insulin for Nasal Administration," <i>Journal of Controlled Release</i> , 1984, vol. 1, pages 15-22, Elsevier Science Publishers B.V., Amsterdam, The Netherlands.		
		ROJANASAKUL et al, "The Transport Barrier of Epithelia: A Comparative Study on Membrane Permeability and Charge Selectivity in the Rabbit," <i>Pharmaceutical Research</i> , 1992, vol. 9, no. 8, pages 1029-1034, Plenum Publishing Corporation.		
		RYDÉN and EDMAN, "Effect of polymers and microspheres on the nasal absorption of insulin in rats," <i>International Journal of Pharmaceutics</i> , 1992, vol. 83, pages 1-10, Elsevier Science Publishers B.V.		
		SHEN et al, "Calu-3: a human airway epithelial cell line that shows cAMP-dependent Cl ⁻ secretion," <i>Am. J. Physiol.</i> , May 1994, vol. 266, no. 5 pt. 1, pages L493-501.		
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		UCHIMAYA et al, "Effects of Various Protease Inhibitors on the Stability and Permeability of [D-Ala ² , D-Leu ⁵]enkephalin in the Rat Intestine: Comparison with Leucine Enkephalin," <i>Journal of Pharmaceutical Sciences</i> , April 1998, vol. 87, no. 4, pages 448-452.		
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		WATANABE et al, "Enhancing Effect of Cyclodextrins on Nasal Absorption of Insulin and Its Duration in Rabbits," <i>Chem. Pharm. Bull.</i> , 1992, vol. 40, no. 11, pages 3100-3104.		
ADK		YAMAMOTO et al, "Effectiveness and Toxicity Screening of Various Absorption Enhancers in the Rat Small Intestine: Effects of Absorption Enhancers on the Intestinal Absorption of Phenol Red and the Release of Protein and Phospholipids from the Intestinal Membrane," <i>J. Pharm. Pharmacol.</i> , 1996, vol. 48, pages 1285-1289.		

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ADK		DREISIN and MOSTOW, "Sulfhydryl-mediated depression of ciliary activity: an adverse effect of acetylcysteine," <i>J. Lab. Clin. Med.</i> , April 1979, vol. 93, no. 4, pages 674-678.		
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ADK		CORBO et al, "Drug Absorption Through Mucosal Membranes: Effect of Mucosal Route and Penetrant Hydrophilicity," <i>Pharmaceutical Research</i> , October 1989, vol. 6, no. 10, pages 848-852.	
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ADK		PARDRIDGE et al, "Enhanced Endocytosis in Cultured Human Breast Carcinoma Cells and <i>In Vivo</i> Biodistribution in Rats of a Humanized Monoclonal Antibody after Cationization of the Protein," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , July 1998, vol. 286, no. 1, pages 548-554.		
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/601,953
		Filing Date	6/24/2003
		First Named Inventor	Quay
		Art Unit	1614
		Examiner Name	
(Use as many sheets as necessary)		Attorney Docket Number	02-03US
Sheet	13	of	15

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ADK		EKRAMI et al, "Disposition of Positively Charged Bowman-Birk Protease Inhibitor Conjugates in Mice: Influence of Protein Conjugate Charge Density and Size on Lung Targeting," <i>Journal of Pharmaceutical Sciences</i> , April 1995, vol. 84, no. 4, pages 456-461.	
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ADK		BROGLIA et al, "Folding and aggregation of designed proteins," <i>Proc. Natl. Acad. Sci.</i> , October 1998, vol. 95, no. 22, pages 12930-12933.	

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ADK		KHAN et al, "Solubilization of Recombinant Ovine Growth Hormone with Retention of Native-like Secondary Structure and Its Refolding from the Inclusion Bodies of <i>Escherichia coli</i> ," <i>Biotechnol. Prog.</i> , September-October 1997, vol. 14, no. 5, pages 722-728.	
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		TOBIO et al, "The role of PEG on the stability in digestive fluids and in vivo fate of PEG-PLA nanoparticles following oral administration," <i>Colloids and Surfaces B: Biointerfaces</i> , October 2000, vol. 18, no. 3-4, pages 315-323.	
		BEZEMER et al, "Microspheres for protein delivery prepared from amphiphilic multiblock copolymers. 1. Influence of preparation techniques on particle characteristics and protein delivery," <i>Journal of Controlled Release</i> , July 2000, vol. 67, no. 2-3, pages 233-248, Elsevier Science B.V.	
		BEZEMER et al, "Microspheres for protein delivery prepared from amphiphilic multiblock copolymers. 2. Modulation of release rate," <i>Journal of Controlled Release</i> , July 2000, vol. 67, no. 2-3, pages 249-260, Elsevier Science B.V.	
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ADK		WITSCHI and MRSNY, "In Vitro Evaluation of Microparticles and Polymer Gels for Use as Nasal Platforms for Protein Delivery," <i>Pharmaceutical Research</i> , March 1999, vol. 16, no. 3, pages 382-390.	

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ADK ↓		CROTTS and PARK, "Protein delivery from poly(lactic-co-glycolic acid) biodegradable microspheres: release kinetics and stability issues," <i>J. Microencapsulation</i> , 1998, vol. 15, no. 6, pages 699-713.	
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ADK		KUO and SALTZMAN, "Novel Systems for Controlled Delivery of Macromolecules," <i>Critical Reviews in Eukaryotic Gene Expression</i> , 1996, vol. 6, no. 1, pages 59-73.	
		AURRAND-LIONS, M.; DUNCAN, L.; BALLESTREM, C.; and IMHOF, B. A.; "JAM-2, a Novel Immunoglobulin Superfamily Molecule, Expressed by Endothelial and Lymphatic Cells;" <i>J Biol Chem</i> ; January 2001; 276 (4); 2733-2741	

Examiner Signature	/Andrew D. Kosar/	Date Considered	08/02/2006
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